TAB B

TITLE VII—MISCELLANEOUS PROVISIONS

SEC. 702. TRADE ACT AUTHORIZATION.—The conference agreement includes language amending section 245 of the Trade Act of 1974, as amended, to authorize appropriations to the Department of Labor through September 30, 2000 of such sums as may be necessary to administer the general TAA and NAFTA-related TAA programs of Chapter 2 of Title II of that Act. The provision caps NAFTA training expenses at $30,000,000.

In addition, the provision amends section 256 of the Trade Act of 1974 to authorize appropriations to the Secretary of Commerce through September 30, 2001 of such sums as may be necessary to administer the TAA for firms program.

The conference agreement would enact the provisions of H.R. 3426 as introduced on November 17, 1999. The text of that bill follows:

A BILL To amend titles XVIII, XIX, and XXI of the Social Security Act to make corrections and refinements in the medicare, medicaid, and State children's health insurance programs, as revised by the Balanced Budget Act of 1997

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BBA; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999".

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) REFERENCES TO THE BALANCED BUDGET ACT OF 1997.—In this Act, the term "BBA" means the Balanced Budget Act of 1997 (Public Law 105–33).

(d) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

(2) exclude the update to the first cost reporting period (from fiscal year 1995 to fiscal year 1998) described in section 1888(e)(3)(B)(i) of such Act (42 U.S.C. 1395yy(e)(3)(B)(i)).

TITLE II—PROVISIONS RELATING TO PART B

Subtitle A—Hospital Outpatient Services

SEC. 201. OUTLIER ADJUSTMENT AND TRANSITIONAL PASS-THROUGH FOR CERTAIN MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.

(a) OUTLIER ADJUSTMENT.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(1) by redesignating paragraphs (5) through (9) as paragraphs (7) through (11), respectively; and

(2) by inserting after paragraph (4) the following new paragraph:

"(5) OUTLIER ADJUSTMENT.—

"(A) IN GENERAL.—Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

"(i) a fixed multiple of the sum of—

"(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

"(II) any transitional pass-through payment under paragraph (6); and

"(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

"(B) AMOUNT OF ADJUSTMENT.—The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

"(C) LIMIT ON AGGREGATE OUTLIER ADJUSTMENTS.—

"(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

"(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term 'applicable percentage' means a percentage specified by the Secretary up to (but not to exceed)—

"(I) for a year (or portion of a year) before 2004, 2.5 percent; and

"(II) for 2004 and thereafter, 3.0 percent.

"(D) TRANSITIONAL AUTHORITY.—In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

"(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

"(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.".

(b) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—Such section is further amended by inserting after paragraph (5) the following new paragraph:

"(6) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—

"(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

"(i) CURRENT ORPHAN DRUGS.—A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

"(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

"(iii) CURRENT RADIOPHARMACEUTICAL DRUGS AND BIOLOGICAL PRODUCTS.—A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

"(iv) NEW MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

"(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

"(II) the cost of the device, drug, or biological is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

"(B) LIMITED PERIOD OF PAYMENT.—The payment under this paragraph with respect to a medical device, drug, or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

"(i) on the first date this subsection is implemented in the case of a drug, biological, or device described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a device, drug, or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

"(ii) in the case of a device, drug, or biological described in subparagraph (A)(iv) not described in clause (i), on the first date on which payment is made under this part for the device, drug, or biological as an outpatient hospital service.

"(C) AMOUNT OF ADDITIONAL PAYMENT.—Subject to subparagraph (D)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

"(i) in the case of a drug or biological, the amount by which the amount determined under section 1842(o) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

"(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

"(D) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—

"(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

"(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term 'applicable percentage' means—

"(I) for a year (or portion of a year) before 2004, 2.5 percent; and

"(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

"(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.".

(c) APPLICATION OF NEW ADJUSTMENTS ON A BUDGET NEUTRAL BASIS.—Section 1833(t)(2)(E) (42 U.S.C. 1395l(t)(2)(E)) is amended by striking "other adjustments, in a budget neutral manner, as determined to be necessary to ensure equitable payments, such as outlier adjustments or" and inserting ", in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as".

(d) LIMITATION ON JUDICIAL REVIEW FOR NEW ADJUSTMENTS.—Section 1833(t)(11), as redesignated by subsection (a)(1), is amended—

(1) by striking "and" at the end of subparagraph (C);

(2) by striking the period at the end of subparagraph (D) and inserting "; and"; and

(3) by adding at the end the following:

"(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments (consistent with paragraph (6)(B)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).".

(e) INCLUSION OF CERTAIN IMPLANTABLE ITEMS UNDER SYSTEM.—

(1) IN GENERAL.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(A) in paragraph (1)(B)(ii), by striking "clause (iii)" and inserting "clause (iv)" and by striking "but";

(B) by redesignating clause (iii) of paragraph (1)(B) as clause (iv) and inserting after clause (ii) of such paragraph the following new clause:

"(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s); but"; and

(C) in paragraph (2)(B), by inserting after "resources" the following: "and so that an implantable item is classified to the group that includes the service to which the item relates".

(2) CONFORMING AMENDMENT.—(A) Section 1834(a)(13) (42 U.S.C. 1395m(a)(13)) is amended by striking "1861(m)(5))" and inserting "1861(m)(5), but not including implantable items for which payment may be made under section 1833(t)".

(B) Section 1834(h)(4)(B) (42 U.S.C. 1395m(h)(4)(B)) is amended by inserting before the semicolon the following: "and does not include an implantable item for which payment may be made under section 1833(t)".

(f) AUTHORIZING PAYMENT WEIGHTS BASED ON MEAN HOSPITAL COSTS.—Section 1833(t)(2)(C) (42 U.S.C. 1395l(t)(2)(C)) is amended by inserting "(or, at the election of the Secretary, mean)" after "median".

(g) LIMITING VARIATION OF COSTS OF SERVICES CLASSIFIED WITH A GROUP.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2)) is amended by adding at the end the following new flush sentence:

"For purposes of subparagraph (B), items and services within a group shall not be treated as 'comparable with respect to the use of resources' if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.".

(h) ANNUAL REVIEW OF OPD PPS COMPONENTS.—

(1) IN GENERAL.—Section 1833(t)(8)(A) (42 U.S.C. 1395l(t)(8)(A)), as redesignated by subsection (a), is amended—

(A) by striking "may periodically review" and inserting "shall review not less often than annually"; and

(B) by adding at the end the following: "The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.".

(2) EFFECTIVE DATES.—The Secretary of Health and Human Services shall first conduct the annual review under the amendment made by paragraph (1)(A) in 2001 for application in 2002 and the amendment made by paragraph (1)(B) takes effect on the date of the enactment of this Act.

(i) NO IMPACT ON COPAYMENT.—Section 1833(t)(7) (42 U.S.C. 1395l(t)(7)), as redesignated by subsection (a), is amended by adding at the end the following new subparagraph:

"(D) COMPUTATION IGNORING OUTLIER AND PASS-THROUGH ADJUSTMENTS.—The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.".

(j) TECHNICAL CORRECTION IN REFERENCE RELATING TO HOSPITAL-BASED AMBULANCE SERVICES.—Section 1833(t)(9) (42 U.S.C. 1395l(t)(9)), as redesignated by subsection (a), is amended by striking "the matter in subsection (a)(1) preceding subparagraph (A)" and inserting "section 1861(v)(1)(U)".

(k) EXTENSION OF PAYMENT PROVISIONS OF SECTION 4522 OF BBA UNTIL IMPLEMENTATION OF PPS.—Section 1861(v)(1)(S)(ii) (42 U.S.C. 1395x(v)(1)(S)(ii)) is amended in subclauses (I) and (II) by striking "and during fiscal year 2000 before January 1, 2000" and inserting "and until the first date that the prospective payment system under section 1833(t) is implemented" each place it appears.

(l) CONGRESSIONAL INTENTION REGARDING BASE AMOUNTS IN APPLYING THE HOPD PPS.—With respect to determining the amount of copayments described in paragraph (3)(A)(ii) of section 1833(t) of the Social Security Act, as added by section 4523(a) of BBA, Congress finds that such amount should be determined without regard to such section, in a budget neutral manner with respect to aggregate payments to hospitals, and that the Secretary of Health and Human Services has the authority to determine such amount without regard to such section.

(m) EFFECTIVE DATE.—Except as provided in this section, the amendments made by this section shall be effective as if included in the enactment of BBA.

(n) STUDY OF DELIVERY OF INTRAVENOUS IMMUNE GLOBULIN (IVIG) OUTSIDE HOSPITALS AND PHYSICIANS' OFFICES.—

(1) STUDY.—The Secretary of Health and Human Services shall conduct a study of the extent to which intravenous immune globulin (IVIG) could be delivered and reimbursed under the medicare program outside of a hospital or physician's office. In conducting the study, the Secretary shall—

(A) consider the sites of service that other payors, including Medicare+Choice plans, use for these drugs and biologicals;

(B) determine whether covering the delivery of these drugs and biologicals in a medicare patient's home raises any additional safety and health concerns for the patient;

(C) determine whether covering the delivery of these drugs and biologicals in a patient's home can reduce overall spending under the medicare program; and

(D) determine whether changing the site of setting for these services would affect beneficiary access to care.

(2) REPORT.—The Secretary shall submit a report on such study to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate within 18 months after the date of the enactment of this Act. The Secretary shall include in the report recommendations regarding the appropriate manner and settings under which the medicare program should pay for these drugs and biologicals delivered outside of a hospital or physician's office.

SEC. 202. ESTABLISHING A TRANSITIONAL CORRIDOR FOR APPLICATION OF OPD PPS.

(a) IN GENERAL.—Section 1833(t) (42 U.S.C. 1395l(t)), as amended by section 201(a), is further amended—

(1) in paragraph (4), in the matter before subparagraph (A), by inserting ", subject to paragraph (7)," after "is determined"; and

(2) by redesignating paragraphs (7) through (11) as paragraphs (8) through (12), respectively; and